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| APPLICATION NO.         | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|-------------------------|------------------|
| 10/663,506              | 09/15/2003  | Muhammad Ashraf      | AM-101106US             | 1850             |
| 38199                   | 7590        | 11/15/2006           | EXAMINER                |                  |
| HOWSON AND HOWSON       |             |                      | CARTER, KENDRA D        |                  |
| CATHY A. KODROFF        |             |                      |                         |                  |
| SUITE 210               |             |                      | ART UNIT                | PAPER NUMBER     |
| 501 OFFICE CENTER DRIVE |             |                      | 1617                    |                  |
| FT WASHINGTON, PA 19034 |             |                      | DATE MAILED: 11/15/2006 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/663,506             | ASHRAF ET AL.       |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Kendra D. Carter       | 1617                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 26 July 2006.

2a)  This action is **FINAL**.                            2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-8 and 10-19 is/are pending in the application.  
4a) Of the above claim(s) 7 and 8 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-8 and 10-19 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_ .

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

**DETAILED ACTION**

The Examiner acknowledges the applicant's remarks and arguments of July 26, 2006 made to the non-final rejection filed May 4, 2006. Claims 1-8 and 10-19 are pending for examination on the merit. Claims 1, 7-8, 10 and 15 were amended. Claim 9 was cancelled and claims 7 and 8 were withdrawn.

In view of applicants amendments to the claims the 35 USC 102(e) rejection of claims 1-6, 9-12 and 15-17 over Zhu et al (US 2002/0055518 A1) is now withdrawn. The 35 USC 103(a) rejection of claims 13-14 and 18-19 over Zhu et al (US 2002/0055518 A1) in view of Rubino et al. (US 2004/0167152 A1) is also withdrawn.

In view of the claim amendments the following new 35 USC 102(e) and 35 USC 103(a) rejections are being made. Since the Obvious Double Patenting rejection was not included in the previous office action, it is now being made, and hence is a new Non-final action. Even though new rejections are being made, Examiner will address Applicant's arguments.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**(1) Claims 1, 2, and 4-6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55, 58-61, 65, and 72-73 of copending Application No. 10/930,487. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.**

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The U.S. Application 10/930,487 teaches a composition comprising an amorphous form of rapamycin 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid, comprising: a metal chelator, a pH adjuster, a surfactant, at least one filler, a binder, a disintegrant, and a lubricant (see claim 55). The pH adjuster comprises citric acid, ascorbic acid, fumaric acid or malic acid (see claims 58-59). The

surfactant is selected from a polysorbate, a sorbitan ester, poloxamer, or sodium lauryl sulfate (see claims 60 and 61). The binder comprises providone, hydroxypropylmethylcellulose, carboxymethylcellulose or gelatin (see claim 65). The composition is dry or wet granulated (see claims 72 and 73).

The U.S. Application 10/930,487 does not teach the specific wordage "water soluble polymer" or "antioxidant", wherein the antioxidant is from 0.001% to 3% (wt/wt).

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising a water soluble polymer and an antioxidant according to 10/930,487 because hydroxypropylmethylcellulose (see claim 72) is a water soluble polymer and ascorbic acid (see claim 58) is an antioxidant. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

In regards to the range of the antioxidant in the composition, it is within the skill of the art to adjust concentrations to obtain desired characteristics. Since there are no reasons disclosed why the particular range of 0.001% to 3% gives results that produce unexpected results, then the ranges of the antioxidant are obvious to one skilled in the art to obtain.

**(2) Claims 1, 2, and 4-6 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 7-8 and 11 of copending Application No. 11/030,685. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.**

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The U.S. Application 11/030,685 teaches a composition comprising micronized CCI-779, surfactant, filler/binder, disintegrant (see claims 1 and 7), one or more antioxidants, a chelating agent, and/or a pH modifier (see claim 11). The surfactant is sodium lauryl sulfate (see claim 8). An oral CCI-779 dosing unit comprises citric acid at 0.08% w/w, BHT at 0.05% w/w, BHA at 0.022% w/w (see claim 23), and hydroxypropylmethylcellulose (see claim 26). The dosing unit is selected from the group consisting of a tablet and a capsule (see claim 27).

The U.S. Application 11/030,685 does not teach the specific wordage "water soluble polymer" or a composition comprising a granulation.

One having ordinary skill in the art would find it obvious to formulate a pharmaceutical composition comprising a water soluble polymer and a composition

comprising a granulation according to 11/030,685 because hydroxypropylmethylcellulose (see claim 26) is a water soluble polymer and the composition is in granular form due to formation of a tablet (see claim 27). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1, 2, 4, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Rubino et. al. (US 2004/0167152 A1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Rubino et. al. teaches a formulation containing CCI-779, composed of CCI-779, an antioxidant, a diluent solvent, and a surfactant (see page 2, column 1, paragraph 16 in its entirety, addresses applicant's claim 1 in part). Acceptable antioxidants include, but are not limited to, citric acid (addresses applicant's claim 6), d,l- $\alpha$ -tocopherol, BHA, BHT, ascorbic acid, and mixtures thereof (see page two, column one, paragraph 18, lines 3-6) ranging from 0.001% to 1% w/v (see page 2, column 1, paragraph 18, lines 6-8; addresses applicant's claim 1 in part). Other components include water, ethanol, polyethylene glycol 300 (see page 2, column 2, paragraph 21, lines 18-19; addresses applicant's claim 1 in part and claim 2). Surfactants are selected from salts of bile acids and ethoxylated vegetable oils (see page 2, column 2, paragraph 21, lines 8-9 and 11).

Although citric acid is disclosed as an antibiotic and polyethylene glycol is disclosed as a surfactant, a chemical composition and its properties are inseparable. "Products of identical chemical composition can not have mutually exclusive properties." Therefore, if the prior art teaches the identical chemical structure, the properties

applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Rubino et. al. discloses range of the antibiotic is w/v, whereas the applicant discloses the antibiotic range in wt/wt. The different measurements are viewed as the same to one ordinarily skilled in the art. The w/v measurements are taken in regards to the co-solvent concentrate, which is water (see page 2, column 1, paragraph 18, lines 7-9 and column 2, paragraph 21, line 18). Since water has a density of 1 g/mL, and the weight of the applicant's composition is taken as a whole (i.e. 1), then the measurements are virtually the same.

In regards to the applicant's composition comprising a granulation, it is inherent that when the components of the applicant's composition is exactly the same as the components of the Rubino et. al. composition, that the compositions will both be granular. Since granulation imposes that the composition be in a solid form with large particles, the prior art meets this limitation due to the fact that the components are (1) identical to the applicant's, and (2) CCI-779 is known to precipitate upon dilution with aqueous infusion solutions (see page 1, column 1, line 17), thus creating a granular composition of the large CCI-779 particles and the other solid component so the composition. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3, 5, and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubino et. al. (US 2004/0167152 A1) as applied to claims 1,2, 4, and 6 above, and in view of Patel et al. (US 6,248,363 B1).

Rubino et. al. (US 2004/0167152 A1) teachings are as applied to claims 1,2, 4, and 6 above.

Rubino et. al. does not teach a composition comprising PVP and sodium lauryl sulfate or sodium dodecyl sulfate.

Azrolan et al. teaches oral formulations of 42-ester with 3-hydroxy-2-(hydroxymethyl)-2-methylpropionic acid (see claim 5 and page 4, column 1, paragraph 26, lines 1-2) comprising for useful tablet formulations sodium lauryl sulfate, polyvinylpyrrolidone, poloxamer 188, sodium dodecyl sulfate, and wet or dry granulation (see page 4, column 1, paragraph 26, lines 10, 11, 16-18, 25, column 2, line 1). For suspensions as a free base or pharmacologically acceptable salt hydroxyl-propyl-cellulose is used (see page 4, column 2, paragraph 28, lines 2-6). For sterile aqueous solutions or dispersions and sterile powders, polyethylene glycol, water, ethanol, and vegetable oils are used (see page 4, column 2, paragraph 29, lines 2-4 and 10-12).

One having ordinary skill in the art at the time the invention was made would have found it obvious to formulate a composition of Rubino et al. comprising PVP and sodium lauryl sulfate or sodium dodecyl sulfate because Azrolan et. al. teaches compositions with the applicant's compound comprising PVP, sodium lauryl sulfate and sodium dodecyl sulfate.

The motivation for a composition comprising PVP and sodium lauryl sulfate or sodium dodecyl sulfate is because Azrolan et. al. teaches that these components are useful for making tablets (see page 4, column 1, paragraph 26, line 10), suspensions

(see page 4, column 2, paragraph 28, line 3), and sterile powders (see page 4, column 2, paragraph 29, lines 2-4). It would be beneficial for the applicant's composition to be made in to a tablet, suspension or sterile powder for use as a medicament. In addition, Rubino et al. states that one of skill in the art may readily select other suitable surfactants (see page 2, column 2, paragraph 21, lines 7-8). Thus, a suitable surfactant and water soluble polymer is chosen based on the type of appearance (i.e. powder, suspension, tablet) or potential use that one of ordinary skill in the art wants to make.

In regards to claims 10-12 and 15-17, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985), see also MPEP § 2113.

For these reasons claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited reference. The claims 3, 5, and 10-19 are therefore properly rejected under 35 USC § 103.

***Response to Arguments***

**(1) Election/Restriction**

Applicant's arguments filed July 26, 2006 have been fully considered.

The Applicants acknowledged the election of claims 1-6 and 9-19 for examination with traverse and withdrew claims 7 and 8 from consideration, but requested that the claims be kept. The rejoinder practice is stated below.

The Examiner has required restriction between product and process claims. If the product claims 1-6 and 10-19 are subsequently found allowable, withdrawn process claims 7 and 8 that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims are maintained. Withdrawn process claims that are not

commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The restriction requirement is maintained FINAL for reasons stated in the office action filed May 4, 2006 and rejoinder of the process claims are acknowledged if the product claims are found to be allowable and within the same scope.

## **(2) Title**

In view of the amendments to the title to reflect the proper name of CCI-779, the title objection is withdrawn.

## **(3) Claim Objection**

In view of the amendments to the claims to reflect the proper name of CCI-779, the claim objection is withdrawn.

## **(4) Claim Rejections – 35 USC § 102(e)**

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Applicant's arguments have been fully considered and found to not be persuasive.

The applicant argues that calcium carbonate is taught by Zhu et. al., but is not claimed in the instant pharmaceutical compositions. This is not persuasive because the open ended "comprising" language as claimed does not exclude agents such as calcium carbonate. In regard to the Examiner's reliance on Zhu et. al. where it is alleged that calcium carbonate acts as an antioxidant, Applicant requests that the Examiner substantiate that calcium carbonate is an antioxidant since Zhu et. al. teaches it to be a "suspending or stabilizing agent".

In regards to the specific use of calcium carbonate as an antioxidant, where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties such as an antioxidant that the applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F. 2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Thus, calcium carbonate taught by Zhu et al serves both as an antioxidant and a suspending or stabilizing agent.

The applicant noted that Zhu et. al. teaches pegylated hydroxyesters of rapamycin whereas the instant invention teaches that CCI-779 exhibits poor aqueous solubility and aqueous instability and that solubility and instability problems can unexpectedly be overcome by the pharmaceutical compositions claimed.

Such an argument is simply not persuasive because the compound having the structure shown on page one, paragraph 8 of Zhu et. al. wherein  $R^1$  is  $CO(CR^3R^4)_b(CR^5R^6)_dCR^7R^8R^9$ ;  $b=0$ ,  $d=1$ ,  $R^5$  and  $R^6$  are each  $-(CR^3R^4)_fOR^{10}$ , wherein  $R^3$ ,  $R^4$ ,  $R^{10}$ , and  $R$  are each hydrogen and  $f=2$  (see page 10, column two, claim 16, for example), is the same compound that the applicant discloses as CCI-779.

The Applicant asserts that the pharmaceutical compositions are not taught by Zhu et al. Therefore, the Applicant argues that any rejections predicted on the process not conferring patentability are inapplicable since Zhu et al. do not teach the pharmaceutical composition.

The argument is not persuasive because Zhu et al. teaches the applicant's composition as stated in the previous office action and above. Thus, the product-by-process claims 10-12 and 15-17 are still rejected because Zhu et al. teaches the applicant's composition.

The 102(e) claim rejection is therefore maintained, but in view of the amendments to the claims to reflect that the antioxidant is from the range of 0.001% to 3% (wt/wt), a new 102(e) claim rejection was made.

**(5) Claim Rejections – 35 USC § 103**

Applicant's arguments filed July 26, 2006 have been fully considered.

For the reasons set forth above in the 102(e) rejection, the applicant argues that Zhu et. al. does not teach the pharmaceutical compositions claimed and therefore does not render the invention obvious. Applicant also notes that at the time the invention was made the claimed inventions were commonly owned with Zhu et. al. In particular, Wyeth, the assignee of the instant invention, acquired American Home Products, the assignee of the Zhu et. al. publication, prior to the making of the instant invention. Thus, Zhu et. al. only qualifies as prior art under 35 USC § 102(e).

The Examiner has found the arguments to be persuasive and thus withdraws the 35 U.S.C. 103(a) rejection.

The applicant notes that Rubino et. al. was published on August 26, 2004, which is well after the priority date and filling date of the instant invention, which is September 17, 2002 and September 15, 2003, respectively.

In response, the Rubino et al. reference has priority to the provisional application July 30, 2002.

The applicant further argues that the reliance on the assertion that a known product is not patentable because the pharmaceutical compositions are not obvious over Zhu et al., in view of Rubino et al and further in view of Madhavi et al. for the

reasons set forth above. Therefore, any rejections predicate on the process not conferring patentability are inapplicable since the pharmaceutical compositions of the instant invention are not obvious.

The Examiner finds the arguments persuasive for the same reasons, but in view of the amended claims and new 35 U.S.C. 103(a) rejection was submitted.

The applicant further notes that Madhavi et al. does not teach or provide motivation to combine BHA or BHT in a pharmaceutical composition comprising CCI-779 because Madhavi et al. teaches that BHA and BHT are extensively used in the food industry. Also, the mere alleged fact that "the antioxidants BHA and BHT... are commonly used and exhibit excellent absorption, metabolism, and excretion" does not render motivation to combine either of these compounds in pharmaceutical compositions comprising CCI-779.

The Examiner has found the arguments to not be persuasive for the reasons stated in the previous office action.

### ***Conclusion***

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kendra D. Carter whose telephone number is (571) 272-9034. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KDC



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER